UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,990	07/14/2003	Scott Cunningham	2850	5967

50855 7590 06/15/2006

UNITED STATES SURGICAL,
A DIVISION OF TYCO HEALTHCARE GROUP LP
195 MCDERMOTT ROAD
NORTH HAVEN, CT 06473

EXAMINER	
POUS, NATALIE R	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,990	CUNNINGHAM ET AL.	
	Examiner	Art Unit	
	Natalie Pous	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/16/03*. 11/20/03
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments/Remarks

Regarding Drawings:

1. Examiner acknowledges submission of amended drawing sheets. The objection to the drawings is withdrawn.

Regarding 35 USC 103 Rejections:

2. Applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5797961) in view of Smith (US 4799484).

Smith et al. (US 5797961) teach a surgical needle comprising the following features:

- An elongated body defining a longitudinal y-axis (5)
- A central shaft portion (40)
- A first suture end portion for attachment to a suture (205)
- A second needled end for penetrating tissue (50)
- The needled portion having three sides (560, 570)
- The needled portion having three cutting edges (564, 565, 600)
- Terminating in a needle point (30)
- Each side including one sole pair of planar surfaces (580, 590) arranged in oblique relation (it is noted that although figure 11 describes a needle with two sides having a sole pair of planar surfaces, figure 5D describes a needle wherein each side (410, 420) has a concave surface, and it is therefore within the scope of the invention to have the oblique planar surfaces of figure 11 on each side)
- A distal shaft transition portion (40) defining a cross section of general triangular character (Column 3, proximate lines 4-8) interconnected by rounded surfaces (Fig. 6)
- At least one of the three sides is substantially planar (560)

Smith et al. (US 5797961) fails to disclose wherein the needle comprises an enlarged transition portion adjacent to central shaft portion where the x-dimension (height) of this portion larger than that of shaft. Smith (US 4799484) teaches a surgical needle with an enlarged (x1) transition portion (12) adjacent to the central shaft portion (16), wherein the x-dimension (height) of this portion (x1) is larger than that of the shaft portion (x2) in order to provide smoothly varying strength and performance characteristics. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the surgical needle of Smith (US 5797961) with a an enlarged transition portion adjacent to the central shaft where the x-dimension (height) of this portion is larger than that of the shaft as taught by Smith (US 4799484) in order to provide smoothly varying strength and performance characteristics to the needle.

5. Claims 1, 2, 3, 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong (US 5030228) in view of Smith (US 4799484) and further in view of Allen (US 5403344).

Wong et al. teach a surgical needle comprising the following features:

- An elongated body defining a longitudinal y-axis (10)
- A central shaft portion (25)
- A first suture end portion for attachment to a suture (30)
- A second needled end for penetrating tissue (11)
- The needled portion having three sides (12, 18, 20)
- The needled portion having three cutting edges (12a, 12b, 12c)

- Terminating in a needle point (P)
- A sole pair of planar surfaces (14, 22) arranged in oblique relation
- The planar surface portions of each side are arranged to intersect along a median plane bisecting a respective side to define a substantially symmetrical concave appearance to the respective side (Column 3, proximate lines 32-35, see fig. 5)
- Two of the cutting edges intersect at the needle point (P) and define an angle of about 22° to about 25° (Column 3, proximate lines 47-48)

Wong fails to disclose wherein:

- Each side defines a general concave surface
- The needle comprises an enlarged transition portion adjacent to central shaft portion where the x-dimension (height) of this portion larger than that of shaft.
- the enlarged transition portion defines a z-dimension (width) greater than a corresponding z-dimension of the central shaft portion

Smith teaches a surgical needle with an enlarged (x1) transition portion (12) adjacent to the central shaft portion (16), wherein the x-dimension (height) of this portion (x1) is larger than that of the shaft portion (x2) in order to provide smoothly varying strength and performance characteristics. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the surgical needle of Wong with a an enlarged transition portion adjacent to the central shaft where the x-

dimension (height) of this portion is larger than that of the shaft in order to provide smoothly varying strength and performance characteristics to the needle.

The combination of Smith and Wong fails to disclose wherein each surface defines a general concave surface. Allen teaches a surgical needle wherein each surface (26) defines a general concave surface in order to allow only the three cutting edges to substantially contact the tissue during cutting and therefore provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Smith and Wong with three sides having a substantially concave shape as taught by Allen in order to allow only the three cutting edges to substantially contact the tissue during cutting and therefore provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area.

6. Claims 1, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen (US 5403344) in view of Smith (US 4799484) and further in view of Wong (US 5030228).

Allen teaches a surgical needle comprising the following features:

- An elongated body defining a longitudinal y-axis (10)
- A central shaft portion (12)
- A first suture end portion for attachment to a suture (22)
- A second needled end for penetrating tissue (14)
- The needled portion having three sides (24)

- The needled portion having three cutting edges (20)
- Terminating in a needle point (18)
- Pair of planar surfaces (25, 26) arranged in oblique relation
- each of the three sides (24) include the planar surface portions (25, 26) arranged in oblique relation
- the planar surface portions of the one side intersect to define an included angle ranging from about 160° to about 175°, more specifically about 170°.

It is noted that according to the specification primary angle θ may be in the range of 30° – 120° but preferably 60°, and secondary angle α may range from 0° to 90°, but is preferably 30° (Column 3, proximate lines 39-43). Thus, in Fig. 7, using the stated preferred angles of θ= 60°, and α= 30°, α extends 15° past θ on either side of planar surface (25), creating an isosceles trapezoid defined by planar surfaces (25, 26, and base of ghost triangle 30 of Fig. 8a), wherein the angle between the ghost base of triangle (30), and planar surface is 15°, and therefore the angle between oblique surfaces 26 and 25 is 165°. Further, in order for the included angle between oblique planar surfaces 25 and 26 to be about 170°, this requires the values of θ and α to change minimally and still be within the stated range of θ = 30° – 120° and α = 0° to 90°. One possible configuration being θ= 60°, and α= 50°, α extends 10° past θ on either side planar surface (25), creating an isosceles

trapezoid defined by planar surfaces (25, 26, and base of ghost triangle 30 of Fig. 8a), wherein the angle between the ghost base of triangle (30), and planar surface is 15°, and therefore the angle between oblique surfaces 26 and 25 is 170°.

Allen fails to disclose wherein the needle comprises an enlarged transition portion adjacent to central shaft portion where the x-dimension (height) of this portion larger than that of shaft. Smith teaches a surgical needle with an enlarged (x_1) transition portion (12) adjacent to the central shaft portion (16), wherein the x-dimension (height) of this portion (x_1) is larger than that of the shaft portion (x_2) in order to provide smoothly varying strength and performance characteristics. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the surgical needle of Wong with a an enlarged transition portion adjacent to the central shaft where the x-dimension (height) of this portion is larger than that of the shaft in order to provide smoothly varying strength and performance characteristics to the needle.

The combination of Allen and Smith fails to disclose wherein each side includes one sole pair of planar surface portions. Wong teaches a surgical needle wherein sides have one sole pair of planar surface portions (14, 22) in order to provide a needle with improved penetration and smaller wound opening that is easy to form (Column 2, proximate lines 7-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Allen and Smith with one

sole pair of planar surface portions on the concave surfaces in order to provide a needle with improved penetration and smaller wound opening that is easy to form.

7. Claims 12-15 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sardelis (US 5730732) in view of Wong (US 5030228) and further in view of Allen (US 5403344).

Sardelis teaches a surgical needle comprising the following features:

- an elongated needle body defining a longitudinal y-axis (50)
- the needle body including a central shaft portion (60)
- a first suture end portion for attachment to a suture (80)
- a second needled end portion for penetrating tissue (70)
- the needled end portion (70) having three sides which intersect to define three cutting edges (90)
- and terminating at a needle point (70)
- the needled end portion further defining an enlarged transition portion (Line 7-7) adjacent the central shaft section with an x-dimension (height) at least substantially equal to a corresponding x-dimension of the central shaft (line 8-8).
- the enlarged transition portion defines an x- dimension (Line 7-7) greater than a corresponding x-dimension (Line 8-8) of the central shaft portion (Fig. 6).

- the enlarged transition portion defines a z- dimension (width) at least substantially equal to a corresponding z-dimension of the central shaft (90, Fig. 5).
- the enlarged transition portion defines a z- dimension greater than a corresponding z-dimension of the central shaft portion (90, Fig. 5).
- The x-dimension and z-dimensions of the enlarged transition portion is defined between adjacent cutting edges (90, fig. 7)

Sardelis fails to disclose wherein each side includes a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side to define a general concave appearance to the respective side.

Wong teaches a surgical needle wherein sides include a pair of planar surface portions (14, 22) arranged in oblique relation and intersecting along a median plane (18) bisecting a respective side to define a general concave appearance to the respective side (Column 3, proximate lines 32-35) in order to provide a needle with improved penetration and smaller wound opening that is easy to form (Column 2, proximate lines 7-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the needle sides of Sardelis with a pair of planar surface portions arranged in oblique relation and intersecting along a median plane bisecting a respective side to define a general concave appearance to the respective side in order to provide a needle with improved penetration and smaller wound opening that is easy to form.

The combination of Sardelis and Wong fails to teach wherein each side has a generally concave appearance. Allen teaches a surgical needle wherein each side includes a pair of planar surfaces (25, 26) arranged in an oblique relation in order to minimize the surface area of the needle in contact with the skin in order to provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area (Column 3, proximate lines 55-60). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the surgical needle of the combination of Sardelis and Wong with planar surfaces arranged in an oblique relation on each side as taught by Allen in order to minimize the surface area of the needle in contact with the skin in order to provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area.

8. Claims 1, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al. (US 5797961) in view of Sardelis (US 5730732).

Smith et al. teaches a surgical needle comprising the following features:

- An elongated body defining a longitudinal y-axis (5)
- A central shaft portion (40)
- A first suture end portion for attachment to a suture (205)
- A second needled end for penetrating tissue (50)
- The needled portion having three sides (560, 570)
- The needled portion having three cutting edges (564, 565, 600)
- Terminating in a needle point (30)

- Each side including one sole pair of planar surfaces (580, 590) arranged in oblique relation (it is noted that although figure 11 describes a needle with two sides having a sole pair of planar surfaces, figure 5D describes a needle wherein each side (410, 420) has a concave surface, and it is therefore within the scope of the invention to have the oblique planar surfaces of figure 11 on each side)
- A distal shaft transition portion (40) defining a cross section of general triangular character (Column 3, proximate lines 4-8) interconnected by rounded surfaces (Fig. 6)
- At least one of the three sides is substantially planar (560)

Smith et al. (US 5797961) fails to disclose wherein the needle comprises an enlarged transition portion adjacent to central shaft portion where the x-dimension (height) of this portion larger than that of shaft, and the x-dimension and z-dimension are defined between adjacent cutting edges. Sardelis teaches a surgical needle with an enlarged transition portion (7) adjacent to the central shaft portion (60), wherein the x-dimension (height) of this portion is larger than that of the shaft portion and the x-dimension and z-dimension are defined between adjacent cutting edges (fig. 7) in order to enhance the strength of the needle. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the surgical needle of Smith with a an enlarged transition portion adjacent to the central shaft where the x-dimension (height) of this portion is larger than that of the shaft as taught by Sardelis in the strength of the needle.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
5/30/06

(JACKIE) TAN-UYEN HO
PRIMARY EXAMINER
6/9/06